Supreme Court, U.S.
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No. 06-1291

# In The Supreme Court of the United States

AMGEN INC.,

*Petitioner,*

v.

HOECHST MARION ROUSSEL, INC. (now known as AVENTIS PHARMACEUTICALS INC.) AND TRANSKARYOTIC THERAPIES, INC. (now known as SHIRE HUMAN GENETIC THERAPIES, INC.),

*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## BRIEF OF CROSS MEDICAL PRODUCTS, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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## INTEREST OF THE *AMICUS CURIAE*[1]

Amicus Cross Medical Products, Inc., a subsidiary of Biomet, Inc., is a pioneer for innovation in the orthopedic biomaterials market. Cross holds numerous patents in this field covering, *inter alia*, reconstructive products and fixation devices, and in particular, spinal fixation products. Similarly, Petitioner develops biomedical products, and holds numerous patents covering its innovations. Because of the complex nature of biomedical devices, and because "language remains an imperfect fit for invention," *Festo Corp. v. Shoketsu Kinsoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002), patent holders in this field particularly rely on the doctrine of equivalents to protect their innovations.

Cross files this *amicus* brief because the Federal Circuit has sharply moved away from this Court's decision in *Festo*, 535 U.S. 722, and has nearly eviscerated the tangentialness exception to prosecution history estoppel. Cross has a vital interest in maintaining its ability to rebut the presumption of estoppel through an appropriate application of that exception. Restoring the test set forth by this Court in *Festo*, 535 U.S. 722, will capture the reality of what takes place during patent prosecution, and will strike the appropriate balance between the patent holder's ability to protect its rights to equivalents and the public's need for notice as to the scope of patent protection.

Like Amgen, Cross has fallen victim to the Federal Circuit's misapplied application of the tangentialness exception to overcoming a presumption of prosecution history estoppel. *See Cross Medical Products, Inc. v.*

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus* states that no counsel for a party has authored this brief, in whole or in part, and that no person or entity, other than *amicus*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief. Letters have been filed with the Clerk of the Court confirming that all parties have consented to the submission of this brief.

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*Medtronic Sofamor Danek, Inc.*, No. 05-1415, 2007 WL 817660 (Fed. Cir. Mar. 20, 2007).

Cross, therefore, has a strong interest in urging the Court to grant review and overturn the Federal Circuit's application of its misguided test for rebutting the prosecution history estoppel presumption, and to restore principles previously articulated by this Court. *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, No. 06-1291 provides the opportunity for this Court to immediately end the Federal Circuit's destruction of the balance this Court created.

## SUMMARY OF ARGUMENT

Departing from the test for rebutting the presumption of prosecution history estoppel that this Court unanimously announced, and the Federal Circuit interpreted and applied *en banc* less than four years ago, the Federal Circuit has now nearly eviscerated the tangentialness exception to prosecution history estoppel. That exception requires the court to evaluate whether the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question.

While giving lip service to evaluating the rationale for an amendment during prosecution, recently the Federal Circuit has considered whether the *resulting amendment itself*—rather than the *reason* the amendment was made—is related to the equivalent. Because prosecution history estoppel is typically invoked only when features of the alleged equivalent are intertwined with the amended subject matter, it is virtually inevitable that the result of the amendment will relate, in some way, to the alleged equivalent.

Accordingly, the Federal Circuit's new test is virtually, if not completely, insurmountable. It therefore contravenes this Court's mandate that the presumption of estoppel not be a "complete bar by another name." *Festo*, 535 U.S. at 741.

This Court should grant certiorari. The Federal Circuit has destroyed the balance between prosecution history

estoppel and the doctrine of equivalents that this Court established in *Festo.* Restoring that balance is vitally important to the security of patent rights.

## ARGUMENT

The Federal Circuit has ignored the principles announced in *Festo Corp. v. Shoketsu Kinsoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), misapplied the test as outlined, and undermined this Court's holding. Review by this Court is urgently warranted.

### I. THIS COURT SHOULD GRANT CERTIORARI TO RESTORE PROPER APPLICATION OF LAW THAT HAS BEEN SUBVERTED BY THE FEDERAL CIRCUIT

#### A. Prosecution History Estoppel As A Limitation On The Doctrine of Equivalents

The doctrine of equivalents is judicial recognition that a patent's scope extends beyond the claim's literal terms to protect an inconsequential variation to a patentable invention. Without the doctrine of equivalents, an "unscrupulous copyist" would be encouraged "to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim," rendering patent rights "hollow and useless." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950).

In an effort to clarify the proper scope of the doctrine, this Court identified prosecution history estoppel as a reasonable limitation on the doctrine of equivalents. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 34 (1997). There the Court instructed the Federal Circuit to "consider whether *reasons* for the portion

of the amendment were offered or not and whether further opportunity to establish such *reasons* would be proper," to assess whether that *reason* is sufficient to avoid estoppel. *Id.* (emphasis added). Although the Court provided guidance to the Federal Circuit concerning the scope of the doctrine of equivalents, it declined to "go[] further and micromanag[e] the Federal Circuit's particular word choice for analyzing equivalence." *Id.* at 40. This Court unequivocally *rejected* the notion that an amendment made during patent prosecution categorically surrenders anything beyond the claim's literal terms. *See id.*

More recently, in *Festo*, this Court struck a balance between prosecution history estoppel and the doctrine of equivalents when it ruled that, if a patentee makes a narrowing amendment during prosecution, there is only a *rebuttable presumption* of estoppel. *Festo Corp.*, 535 U.S. at 740. The Court established that a patentee could overcome the presumption that prosecution history estoppel bars the doctrine of equivalents "where the amendment cannot reasonably be viewed as surrendering a particular equivalent." *Id.* The Court set forth specific criteria that must be considered when determining if prosecution history estoppel applies. *Id.* at 740-41.

### B. Prosecution History Estoppel Does Not Bar The Doctrine Of Equivalents If The Reason For the Narrowing Amendment Is Tangential To The Accused Equivalent

Acknowledging the importance of the doctrine of equivalents, this Court reasoned that "[a]fter amendment, as before, language remains an imperfect fit for invention," and ruled that "[t]he amendment does not show that the inventor suddenly had more foresight in the drafting of claims than an inventor whose application was granted without amendments

having been submitted." *Festo*, 535 U.S. at 738. Further, this Court recognized that "there is no more reason for holding the patentee to the literal terms of an amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent." *Id.*

The Court then enumerated instances in which prosecution history estoppel would not apply following a narrowing amendment, including where "the rationale underlying the amendment [bears] no more than a tangential relation to the equivalent in question."[2] *Id.* at 740.

After remand, the Federal Circuit, writing *en banc*, explained that the tangentialness criterion "asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) ("*Festo III*"). Thus, this exception "focuses on the patentee's objectively apparent reason for the narrowing amendment." *Id.*

For a short time following this Court's *Festo* decision, the tangentialness test was properly applied to determine whether that exception to prosecution history estoppel had been met. For example, in *Insituform Techs. v. CAT Contracting, Inc.*, the Federal Circuit stated: "The question we must address is 'whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the

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[2] The Court also stated that prosecution history estoppel would not apply to a narrowing amendment when the equivalent was "unforeseeable at the time of the application," or where there was "some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-41. However we not aware of any case where the Federal Circuit applied either the foreseeability test or the rarely invoked residual criterion to rebut prosecution history estoppel. Therefore, the tangential relationship test is the most important *Festo* criterion for maintaining balance between the doctrine of equivalents and prosecution history.

alleged equivalent.'" 385 F.3d 1360, 1370 (Fed. Cir. 2004) (quoting *Festo III*, 344 F.3d at 1365).

*Insituform* involved a process in which resin was drawn through a tube. The claims, as originally drafted, "would likely have read on a process using . . . multiple [vacuum] cups . . . at any location downstream of the resin . . . ." *Insituform Techs., v. CAT Contracting, Inc.*, 99 F.3d 1098, 1108 (Fed. Cir. 1996). But the claims were amended to avoid the need for a large vacuum compressor at the end of the tube. *Id.* To that end, the amendment added a limitation requiring a single vacuum source located at a point along the tube near the resin. The proximity of the vacuum source to the resin allowed the use of a smaller vacuum. *Id.* Thus, the amended claim was "literally limited to the use of one vacuum cup . . . ." *Id.* at 1108. This claimed design required the single vacuum source to be moved to various positions along the length of the tube as the resin was drawn.

The accused device achieved the same goal as the claimed invention (avoiding the need for a large vacuum compressor at the end of the tube), but did so by placing several vacuums along the length of the tube, each one being removed as the resin was drawn. *Id.* The *Insituform* patentee never indicated that the large vacuum source could be eliminated only in the manner set forth by its added limitation. *Id.*

The Federal Circuit determined that because the *reason* for the amendment was directed towards other prior art, and not the equivalent in question, the amendment and the equivalent were no more than tangentially related, and thus the doctrine of equivalents could apply. *Insituform*, 385 F.3d at 1370. The Federal Circuit appropriately interpreted the scope of the alleged equivalent in *Insituform* to encompass only the *number* of vacuum sources, while the reason for the amendment was to distinguish prior art with respect to the *location* of the vacuum source. *See id.* at 11.

### C. The Federal Circuit's Application of The Tangentialness Exception Has Undergone A Transformation And Is Not Consistent With This Court's Precedents

The Federal Circuit has now departed from proper application of the tangentialness test, as outlined in *Festo*, 535 U.S. at 737 and *Festo III*, 344 F.3d at 1369. The Federal Circuit's new rule does not focus on the *reason* for the narrowing amendment, but instead focuses on the *result* of the amendment itself.

In the case presently on petition before this Court, the Federal Circuit has not merely misapplied a properly stated rule of law, but has changed the governing standard for analyzing whether an amendment during prosecution is tangentially related to the alleged equivalent. *Amgen Inc. v. Hoechst Marion Roussel, Inc., et al.*, 457 F.3d 1293, 1313 (Fed. Cir. 2006). In *Amgen*, the court relied on a narrowing amendment that *resulted* in a claim limited to EPO having the "complete 166-amino acid sequence," and concluded that this *result* was determinative of the *reason* for the amendment. The court of appeals brushed aside significant evidence that the actual *reason* for the amendment was "to avoid a double patenting rejection in light of the '933 patent." *Id.* at 1314-15. The court explicitly acknowledged that the limitation added in the preliminary amendment "may have been central to overcoming a double patenting rejection," yet it still relied solely on the *result* of the amendment to conclude that the amendment was not "merely tangential to the alleged 165-amino acid equivalent." *Id.* at 1315. The Federal Circuit specifically signaled its intent to change the legal landscape concerning the doctrine of equivalents when it incorrectly quoted this Court's *Festo* decision for the "narrow ways" to rebut the presumption of prosecution history estoppel. *Id.* at 1310. Nowhere did this

Court ever state, or even imply, that the enumerated methods for rebutting the prosecution history estoppel presumption should be "narrowly" applied.

Similarly, in *Cross Medical Products, Inc.*, 05-1415, 2007 WL 817660, the Federal Circuit committed the same analytical error as it did in *Amgen*. The court of appeals first ascertained the *reason* for the amendment, as it was required to do under this Court's *Festo* decision. *Id.* at *7. But the court of appeals failed to apply the *reason* for this amendment, and—departing from both this Court's precedent and the Federal Circuit's en banc *Festo III* decision—applied the same fundamentally incorrect test as used in *Amgen* for determining whether estoppel was rebutted: Whether the accused equivalent relates to *the result of the amendment itself*. *Id.*

*Cross Medical* involves a patent that describes a bone screw that is used in spinal surgery. *Id.* at *1. As shown in a figure taken from the patent and reproduced in the court of appeals' opinion itself (shown below), the preferred embodiment of the '555 Patent includes a cap (25) between the compression nut and the rod. *Id.* at *6. In the preferred embodiment, it is this cap, rather than the nut, that contacts the rod. *Id.* at *4.

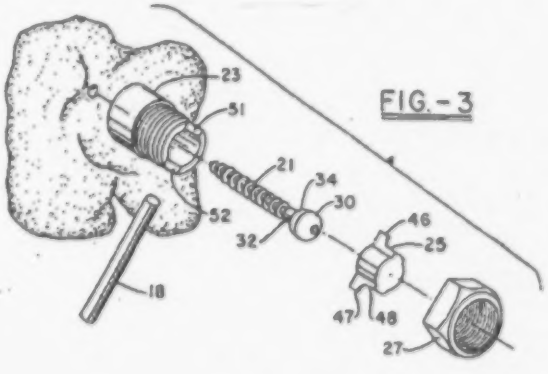

FIG. - 3

All of the original claims of the '555 Patent required the use of a cap. Non-Confidential Joint Appendix, *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 at A2284-87 (Dec. 12, 2005). But during prosecution, Cross added additional claims that did not require that a cap be used between the nut and the rod. *Id.* at A2314-18. Claim 5 was one of the claims that was added during prosecution. *Id.*

Claim 5 (originally Claim 15) was rejected, *inter alia*, under 35 U.S.C. § 112 because the claim failed "to provide an enabling description of the embodiment of the action device excluding the cap/cap means." Non-Confidential Joint Appendix, *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No. 05-1415 at A2327 (Dec. 12, 2005). The claim was amended to add the limitation at issue in *Cross Medical*, which required that the threads of the anchor seat extend towards the bone interface "to a depth below the diameter of the rod." *Cross Medical Products, Inc.*, 05-1415, 2007 WL 817660 at *4. Medtronic, attempting to avoid this limitation, redesigned its bone screw by "'replac[ing] the threads below the top of the rod with a groove or 'undercut.'" *Id.* at *6 (quoting *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No. SA CV 03-110 GLT (ANx), 2005 WL 5239258 at *3 (Apr. 11, 2005) (unpublished)).

The district court, after examining the *reason* for Cross' amendment, ruled that the rationale was no more than tangentially related to Medtronic's redesigned screws:

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> "The rationale behind the amendment [to claim 5] was to adequately describe and enable a device, under § 112, in which the securing means could secure the rod without the use of a cap. The applicant was not attempting to overcome prior art using an undercut, and the amendment did not relate to an undercut. Therefore, the rationale was no more than tangentially related to Medtronic's new screw design, in which threads extend part of the way toward the rod and an undercut extends to a depth below the top of the rod."

*Cross Medical Products, Inc.*, 05-1415, 2007 WL 817660 at *4 (quoting *Cross Medical Products, Inc.*, 2005 WL 5239258 at *5).

The Federal Circuit credited the district court's reasoning as correct. *Cross Medical Products, Inc.*, 05-1415, 2007 WL 817660 at * 7. The court of appeals agreed that "the patentee narrowed claim 5 to address a § 112 rejection." *Id.* But then, rather than examine if Medtronic's accused equivalent relates to this *reason*, the court instead determined that "the accused equivalent . . . relates to the amendment . . . ," and thus applied prosecution history estoppel. *Id.* ("Thus, the accused equivalent, which does not include threads extending 'to a depth below the top of the stabilizer' and correspondingly does not capture this aspect of the invention *relates to the amendment* as shown even by the applicant's own statements.") (emphasis omitted, emphasis added).

Evidencing the Federal Circuit's sharp departure from this Court's careful balancing in *Festo*, 355 U.S. at 740, the Federal Circuit in *Cross Medical* reaffirmed its new "principle that the tangential relation criterion for overcoming the *Festo* presumption is *very narrow*." *Cross*

*Medical Products, Inc.*, 05-1415, 2007 WL 817660 at *5. (emphasis added).

Further, the basis for the decision in *Cross Medical* could not possibly have been that the *reason* for the amendment relates to the equivalent. The court of appeals ruled that "the prosecution history explains that the thread depth limitation was added to capture the manner in which the stabilizer aspect of the invention operated . . . ." *Id.* at *7. The "stabilizer" is the rod (18), and Medtronic's undercut is completely unrelated to how the rod operates. Medtronic even admitted that the undercut "doesn't change the functionality at all. The thread continues down until it can push against the rod in either case." *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No. SA CV 03-110 GLT (ANx), 2005 WL 5239258 at *6. Thus, even if the result of the amendment relates to an undercut, *the reason* for the amendment certainly does not.

Underscoring the fact that the Federal Circuit's new "relates to" test is impassable, the Panel supported its decision in *Cross Medical* by noting that "the prosecution history of the '555 patent shows a narrowing amendment that also 'contains the equivalent in question.'" *Cross Medical Products, Inc.*, 05-1415, 2007 WL 817660 at *6 (quoting *Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005)). But in virtually every case in which prosecution history estoppel is at issue, the narrowing amendment will contain the equivalent in question. That is, after all, the very reason defendants assert prosecution history estoppel.

This test is contrary to both the letter and the spirit of the this Court's decision in *Festo*. This Court ruled that *the rationale* underlying the amendment—not the amendment itself—must bear no more than a tangential relation to the equivalent in question. *Festo*, 355 U.S. at 740. This Court's reasoning in *Festo* clearly envisions that there will be situations in which the result of the amendment is directly

related to the claimed equivalent, but the *reason* for the amendment is no more than tangentially related to the equivalent design. By abandoning that critical distinction between the *scope* of an amendment and the *reasons* for that amendment, the Federal Circuit has effectively embraced the position that this Court explicitly rejected in *Festo*. The court of appeals has created a test for prosecution history estoppel that is effectively insurmountable—thereby contravening this Court's mandate that "[t]his presumption is not, then, just the complete bar by another name." *Id.*, at 741. As the district court in *Amgen* observed, "the correct inquiry is not whether the amendment itself narrows the scope of a claim in a way that affects the equivalent in question. If this were the test, it would be an impassable one—the only reason why the dispute arises is because the equivalent is related to the amendment and affected thereby." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 150 (D. Mass. 2003).

Moreover, the "relates to" test that was applied in both *Amgen* and *Cross Medical* cannot be reconciled with the *Festo III* decision, where the Federal Circuit held that "the inquiry into whether a patentee can rebut the Festo presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment.'" *Festo III*, 344 F.3d at 1369. Indeed, if the test is whether the result of the amendment itself—not the reason for the amendment—"relates to" the equivalent, then there is no need to consider, let alone focus on, the patentee's objectively apparent reason for the narrowing amendment.

The concurring opinion in *Cross Medical* points out that only twice has the Federal Circuit invoked the tangential principle to rebut prosecution history estoppel. *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, No.05-1415, 2007 WL 817660 at * 10 (Judge Rader concurring). After stating that both of those cases "arguably

related to situations where the prosecution history clearly demonstrated that the alleged equivalent and the narrowing amendment implicate entirely different aspects of the invention," the opinion notes that "frankly, this court might well have justifiably reached a different result in both." *Id.* This observation is certainly accurate in light of the test employed in *Cross Medical* and *Amgen*, and highlights the need for review by this Court.

## CONCLUSION

*Amicus* respectfully urges this Court to grant the petition for a writ of certiorari.

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